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*This English version is intended to be a reference material to provide convenience for users. In the event of inconsistency between the Japanese original and this English translation, the former shall prevail.*

# Revision of Precautions

## Preparations containing gardenia fruit (OTC drugs) (oral dosage form)

### **Non-proprietary name**

Preparations containing gardenia fruit (OTC drugs) (oral dosage form)

### **Safety measure**

Precautions should be revised in the package insert.

In the Consultation section, the following text should be added (underlined parts are revised):

If the following symptoms are observed after using this drug, these may be adverse reactions. So, immediately discontinue the use, and show this document to your physician, pharmacist, or registered distributor for a consultation.

The following serious symptoms occur infrequently. Immediately seek medical aid if you experience any of these signs and symptoms.

Mesenteric phleboscrosis:

Abdominal pain, diarrhoea, constipation, abdominal distension, and other signs and symptoms repeatedly occur with long-term administration.

Contact a physician, pharmacist, or registered distributor for a consultation when long-term use of this drug is needed.

Note: Except when products already have the text included in the section